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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/066,224	02/01/2002	Kazuo Sakuma		5335

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Kazuo Sakuma
2119-1, Kaminayoro, Shimokawa-Chou
Kamikawa-gun, Hokkaidou, 098-1216
JAPAN

EXAMINER	
DAVIS, RUTH A	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/066,224	SAKUMA, KAZUO	
	Examiner	Art Unit	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *13-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 25-27* is/are rejected.

7)☒ Claim(s) *1,10,25* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1 – 12 and 25 – 27 in the reply filed on April 24, 2004 is acknowledged.

Claims 13 – 24 are withdrawn from consideration, as being drawn to non elected subject matter.

Specification

2. The abstract of the disclosure is objected to because the abstract should be a single paragraph and should avoid legal phraseology used in patent claims (MPEP 608.01(b) C). The abstract should be combined into a single paragraph and the term "said" in lines 4 and 5 should be removed. Correction is required. See MPEP § 608.01(b).

3. The disclosure is objected to because of the following informalities: The specification does not contain a brief description of figures 23 – 24. See MPEP 608.01(f).

Appropriate correction is required.

Claim Objections

4. Claims 1, 10 and 25 are objected to because of the following informalities:

In claim 1, line 4, the term "ALT" should be spelled properly as "ATL".

In claim 10, line 2, the term "consisting" should be inserted after the term "group", to comply with proper Markush language.

In claim 10, line 3, the abbreviation MRSA should first be spelled out, followed by the abbreviation in parenthesis.

In claim 10, line 3, a "," should be inserted before the term "Streptococcus".

Claim 25 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to multiple claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1 – 12 and 25 – 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, line 1, "The preventative" lacks sufficient antecedent basis.

In claim 1, line 3, "the microbes" lack sufficient antecedent basis.

Claim 1 and its dependents appear to be drawn to a composition comprising Kabanoanatake extracts, however is rendered vague and indefinite for reciting "various syndromes possibly caused by", because it is unclear what syndromes the compositions is

effective for. Specifically, it is unclear if the composition must have preventative and/or therapeutic effects on syndromes that are caused by HIV, retroviruses, ALT or pathogenic bacteria; or if the composition must have effects on any syndrome that may or may not be caused by HIV, retroviruses, ALT or pathogenic bacteria. The claim fails to clearly define what activity and/or effect the composition must have to meet the limitation of the claim. Moreover, the claims are so unclear, it is not possible to clearly ascertain the scope of the invention.

Claims 7 and 8 are rendered vague and indefinite for reciting "strong suppressive effect" because the term "strong" is a term of degree whereby applicant fails to disclose a standard by which one in the art would ascertain what constitutes a "strong suppressive effect" versus a "suppressive effect" on HIV activity and infection. Furthermore, the art does not provide a standard such that one in the art would be apprised of the scope of the claim.

Claim 11 is considered indefinite because it is unclear if the microbe is the ATL retrovirus alone, or if the microbe is a combination of the ATL virus and an additional retrovirus. Since ATL is a retrovirus, it is unclear if the claim is merely further classifying the ATL virus, or if the claim is intended to encompass any retrovirus in addition to the ATL virus.

In claim 26, line 1, "for HIV" lacks sufficient antecedent basis.

Claim 27 is rendered vague and indefinite for reciting "anti-microbial-related syndrome activity" because this phrase is not defined by the claim language or specification. It is unclear what the phrase intends to include or exclude from the scope of the claimed invention.
Claim 27 is further indefinite for reciting "said Kabanoanatake extracts are enabled...by using vehicles or solution." because it is unclear if the Kabanoanatake extracts of the composition must already exhibit antimicrobial activity, or if the vehicles or solutions cause the extract to become

antimicrobial. Moreover, it is unclear if the vehicles or solutions must impart antimicrobial activity to the composition; or if the claim is merely drawn to a composition comprising Kabanoanatake extracts and a carrier.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1 – 12 and 25 – 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As stated above, the claims are extremely unclear as to the scope of the claimed invention. It is unclear if applicant is claiming an extract that has preventative effects against HIV, and/or other unspecified "various syndromes" that may or may not be caused by HIV, retroviruses, ATL or pathogenic bacteria. However, if applicant does intend to claim a composition that comprises Kabanoanatake extracts, wherein the composition has preventative and therapeutic effects against HIV, retroviruses, ATL and pathogenic bacteria, then the claims fail to comply with the enablement requirement. Preventative effects (or prevention) provides for an expectation that a disease or disorder does not occur in response to an initiating event. While there is no requirement that prevention must be absolute in all cases, there is a reasonable expectation that some element of prevention can be shown. The standard for showing prevention

or preventative effects is very high. The standard of enablement is higher for inventions requiring prevention or preventative effects in disease conditions, since such effects may be unbelievable absent strong supporting evidence. Claims drawn to compositions with preventative effects generally require evidence because of the unpredictability in biological responses to therapeutic treatments.

It is well known in the art that retroviral infections, particularly HIV, are generally refractory to anti-viral therapies. The obstacles to HIV therapy and preventatives are well documented in the literature. Examples of such obstacles include the inability of current vaccine designs to elicit effective neutralizing antibodies against circulation strains of HIV or to prevent HIV from establishing persistent infection; the extensive global variability of HIV; and a lack of a practical animal model system for HIV (See Klausner et al., p.2036 and Desrosiers, entire document). The existence of these obstacles establish that the state of the art does not provide a level of predictability such that one in the art would know how to use the claimed extracts without undue experimentation.

Applicant has not provided convincing evidence that Kabanoanatake extracts or a pharmaceutical composition thereof is preventative or therapeutic against HIV infection. The specification is absent actual working examples of how the claimed extract would exhibit preventative and/or therapeutic effects against HIV, retroviruses ATL and/or pathogenic bacteria. The specification fails to teach how to administer the claimed extract in terms of dose, duration and methodology such that one in the art could use the claimed extract to prevent and/or treat the claimed diseases. For example, there is no teaching of administering Kabanoanatake extracts to HIV infected subjects as a pharmaceutical composition against HIV infection. There is no

teaching for what type of biological effects the claimed extract would generate upon the administration, and there is no teaching in the specification whether the immune response generated would be sufficient to treat and/or prevent HIV infection. A person of ordinary skill in the art would not immediately recognize that administering the claimed Kabanoanatake extracts would have a chance of preventing the claimed diseases. It would place an undue burden of experimentation on the person of ordinary skill in the art to find suitable methodologies of administering the claimed extracts, such that the diseases would be prevented and/or treated. Thus, the specification fails to provide sufficient guidance to allow one in the art to use the claimed invention without undue experimentation. Therefore, absent of such guidance and evidence, the specification fails to provide an enabling disclosure.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1 – 12 and 25 – 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Sakuma (JP 10-120589).

Applicant appears to claim a therapeutic composition comprising Kabanoanatake extracts, wherein the composition has therapeutic and preventative effects against HIV, retrovirus, ALT or pathogenic bacteria. The Kabanoanatake is natural, artificially cultured, sawdust cultured, or liquid cultured. The composition is specifically effective against HIV, has suppressive effects on HIV mediated syncytium formation and inhibitory effects against HIV infection at a concentration of 35 ng/ml or at over 0.01 micrograms/ml. The composition is specifically effective against pathogenic bacteria selected from E. coli, Klebsiella pneumoniae, Pseudomonas aeruginosa, MR Staphylcoccus aureus, Streptococcus and Clostridium perfringens. Alternatively, the composition is effective against retrovirus and ATL; or Helicobacter pylori. The composition can be administered orally, anally or vaginally and is a solid, fluid or liquid, is effective against HIV and is administered with a vehicle or solution.

Sakuma teaches compositions comprising extracts of Fuscoporia oblique (Kabanoanatake), wherein the composition has antibacterial and antimicrobial effects against E. coli, K. pneumoniae, P. aeruginosa, S. aureaus and gas gangrene microbe (or C. perfringens) (means to solve the problem, 0005, Table 1). Sakuma teaches the extracts also have suppressive effects against AIDS (or HIV) (0005). The Fuscoporia is natural, artificially cultured, sawdust cultured, or liquid cultured (claims 1-5, 0006), and is orally administered as a powder or solution (claims 10-11).

Although Sakuma does not teach the composition wherein it is effective against HIV at the claimed concentrations, any retrovirus, ATL, or Helicobater pylori, the instant claims recite the same therapeutic agent as disclosed in the prior art. The intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use

is inherent in the reference composition. Moreover, the claiming of a new use, function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable (MPEP 2112 I). In order to be limiting, the intended use must create a structural difference between the claimed composition and the composition of the prior art. In the instant case, the intended use fails to create a structural difference, thus, the intended use is not limiting. Furthermore, it is noted that Sakuma teaches the active extracts can be obtained by extracting the Fuscoporia in hot water (0016). Applicant also obtains the active extracts by extracting the Kabanoanatake (Fuscoporia) in hot water (specification p.4). Thus the compositions are the same. Please note that when applicant claims a composition in terms of function, and the composition of the prior art appears to be the same, the Examiner may make rejections under both 35 U.S.C 102 and 103 (MPEP 2112).

Thus, the reference anticipates the claimed subject matter.

11. Claims 1 – 12 and 25 – 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Sakuma et al. (JP 09-191891).

Applicant appears to claim a therapeutic composition comprising Kabanoanatake extracts, wherein the composition has therapeutic and preventative effects against HIV, retrovirus, ALT or pathogenic bacteria. The Kabanoanatake is natural, artificially cultured, sawdust cultured, or liquid cultured. The composition is specifically effective against HIV, has suppressive effects on HIV mediated syncytium formation and inhibitory effects against HIV infection at a concentration of 35 ng/ml or at over 0.01 micrograms/ml. The composition is specifically effective against pathogenic bacteria selected from E. coli, Klebsiella pneumoniae,

Pseudomonas aeruginosa, MR Staphylcoccus aureus, Streptococcus and Clostridium perfringens. Alternatively, the composition is effective against retrovirus and ATL; or Helicobacter pylori. The composition can be administered orally, anally or vaginally and is a solid, fluid or liquid, is effective against HIV and is administered with a vehicle or solution.

Sakuma teaches compositions comprising extracts of Fuscoporia oblique (Kabanoanatake), wherein the compositions have anti-HIV activity (abstract, 0005). The extracts are effective at 35 ng/ml and 0.01 micrograms/ml (claims1-4, 0006), are from the black portion (or natural, as defined by applicant, spec. page 10), artificially cultured, sawdust cultured or liquid cultured (claims 6-8, 0004, 0007). Sakuma teaches the compositions combined with beverages or food (or vehicles and solutions) that are administered orally (claims 15-18).

Although Sakuma does not teach the composition wherein it is effective against the claimed pathogenic bacteria, any retrovirus, ATL, or Helicobater pylori, the instant claims recite the same therapeutic agent as disclosed in the prior art. The intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. Moreover, the claiming of a new use, function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable (MPEP 2112 I). In order to be limiting, the intended use must create a structural difference between the claimed composition and the composition of the prior art. In the instant case, the intended use fails to create a structural difference, thus, the intended use is not limiting. Furthermore, it is noted that Sakuma teaches the active extracts can be obtained by extracting the Fuscoporia in hot water (0016). Applicant also obtains the active extracts by extracting the Kabanoanatake (Fuscoporia) in hot water (specification p.4). Thus the

compositions are the same. Please note that when applicant claims a composition in terms of function, and the composition of the prior art appears to be the same, the Examiner may make rejections under both 35 U.S.C 102 and 103 (MPEP 2112).

Thus, the reference anticipates the claimed subject matter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ruth A. Davis
February 14, 2005
AU 1651